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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,342	08/01/2003	Jonathan C. Makielski	960296.98989	4060

26734 7590 11/17/2006

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MADISON, WI 53701-2113

EXAMINER

PAK, MICHAEL D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/632,342

Applicant(s)

MAKIELSKI ET AL.

Examiner

Michael Pak

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 30-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Seq comparison attachment</u> .        |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I, SEQ ID NO:7 in the reply filed on August 31, 2006 is acknowledged. The traversal is on the ground(s) that claims 45-47 should be grouped with Group I because the methods use the cells of group I. This is not found persuasive because claims 45-47 are grouped where the classification is separate. Applicants further argue that claim 48 should not be classified in both Group V and VI. Examiner agrees and will group claim 48 separately in a new Group VII drawn to method for determining a biological sample using polynucleotide probe or primers, classified in Class 435, subclass 6. Applicants further argue that separate restriction of sequences is not necessary because the specification on paragraph 29 describe the sequence relationships. However, each sequence must be searched in many databases separately and is a burdensome search.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-50 are pending. Claims 3-6, 8-9, 11-12, 14-15, 21-22, 24, 26, and 30-50 are withdrawn. Claims 1-2, 7, 10, 13, 16-20, 23, 25, and 27-29 are examined.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

Art Unit: 1646

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-2, 7, 10, 13, 16-20, 23, 25, and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Splawski et al. (US 6,342,357).

Splawski et al. disclose nucleic acid encoding SCN5A sodium channel (SEQ ID NO:4) which has an alteration at amino acid 552 of the claimed SEQ ID NO:8 encoded by the nucleic acid (columns 4-8; see attached sequence comparison). Splawski et al. disclose nucleic acid encoding SCN5A (SEQ ID NO:4) which has 99.5% amino acid sequence identity to the claimed SEQ ID NO:8 encoded by the nucleic acid (see sequence comparison attachment). Splawski et al. disclose vectors comprising the nucleic acid of above and cells comprising the vectors (columns 9-12).

4. No claims are allowed. Claims 17-18 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1646

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
12 October 2006

Seq Comparison ATTACHMENT

US-10-632-342-8.ra1

Tue Sep 12 15:23:44 2006

100	1513.5	14.4	1873	1	US-08-336-257A-7	Sequence 7, Appli
101	1512	14.4	2509	1	US-08-149-097D-35	Sequence 35, Appli
102	1506.5	14.4	1912	2	US-09-495-714C-2	Sequence 2, Appli
103	1498.5	14.3	2546	2	US-09-949-016-9501	Sequence 9501, Ap
104	1498.5	14.3	2546	2	US-09-949-016-9501	Sequence 36, Appl
105	1498	14.3	2265	1	US-08-149-097D-36	Sequence 44, Appl
106	1492	14.2	2262	2	US-09-269-446D-44	Sequence 10, Appl
107	1474.5	14.1	2336	3	US-09-268-163-10	Sequence 10, Appl
108	1474.5	14.1	2336	3	US-09-268-163-10	Sequence 8, Appli
109	1468.5	14.0	2237	3	US-10-033-026-8	Sequence 8, Appli
110	1468.5	14.0	2237	3	US-10-033-026-8	Sequence 6, Appli
111	1468.5	14.0	2339	3	US-09-268-163-6	Sequence 48, Appl
112	1468.5	14.0	2339	3	US-08-455-543A-48	Sequence 48, Appl
113	1467.5	14.0	2237	1	US-08-223-305C-48	Sequence 47, Appl
114	1467.5	14.0	2237	1	US-08-455-543A-47	Sequence 47, Appl
115	1467.5	14.0	2339	1	US-08-223-305C-47	Sequence 4, Appli
116	1467.5	14.0	2339	1	US-09-268-163-4	Sequence 2, Appli
117	1467.5	14.0	2343	3	US-10-033-026-4	Sequence 6, Appli
118	1467.5	14.0	2343	3	US-08-713-118-2	Sequence 2, Appli
119	1464.5	14.0	2337	2	US-09-452-007-2	Sequence 6, Appli
120	1464.5	14.0	2337	2	US-07-998-289B-6	Sequence 23, Appl
121	1378	13.1	452	2	US-08-605-284B-23	Sequence 12, Appl
122	1356	12.9	311	2	US-08-605-284B-12	Sequence 14, Appl
123	1339.5	12.8	310	2	US-08-605-284B-14	Sequence 13, Appl
124	1325.5	12.6	310	2	US-08-605-284B-13	Sequence 10, Appl
125	1311.5	12.5	310	2	US-08-605-284B-10	Sequence 5, Appli
126	1308.5	12.5	310	2	US-08-605-284B-5	Sequence 15, Appl
127	1301.5	12.4	309	2	US-08-605-284B-15	Sequence 6, Appli
128	1292.5	12.3	310	2	US-08-605-284B-6	Sequence 4, Appli
129	1263.5	12.0	309	2	US-08-605-284B-4	Sequence 25, Appl
130	1257.5	12.0	309	2	US-08-605-284B-4	Sequence 8322, Ap
131	1239	11.8	413	1	US-09-949-016-8322	Sequence 2, Appli
132	1187.5	11.3	1666	2	US-08-605-284B-16	Sequence 13, Appl
133	1184.5	11.3	310	2	US-09-367-794-2	Sequence 19, Appl
134	1092	10.4	211	3	US-07-745-206A-13	Sequence 19, Appl
135	1050.5	10.0	1754	1	US-08-311-363-13	Sequence 18, Appl
136	1050.5	10.0	1754	1	US-08-605-284B-18	Sequence 6, Appli
137	973	9.3	307	2	US-09-024-020B-6	Sequence 17, Appl
138	952	9.1	311	2	US-09-425-043-6	Sequence 52, Appl
139	839	8.0	232	2	US-08-605-284B-17	Sequence 21, Appl
140	839	8.0	232	2	US-09-398-522-52	Sequence 20, Appl
141	771	7.4	317	2	US-09-041-886-21	Sequence 15, Appl
142	747	7.1	1207	2	US-08-311-363-15	Sequence 3, Appli
143	735	7.0	1182	2	US-08-374-077C-3	Sequence 3, Appli
144	672.5	6.4	312	2	US-08-895-590-3	Sequence 4, Appli
145	668.5	6.4	823	1	US-08-895-590-4	Sequence 4, Appli
146	668.5	6.4	823	1	US-08-895-590-4	Sequence 23, Appl
147	664.5	6.3	785	2	US-10-162-012-17	Sequence 17, Appl
148	664.5	6.3	785	2	US-07-745-206A-15	Sequence 657, Ap
149	664.5	6.3	785	2	US-08-374-077C-3	Sequence 4, Appli
150	594	5.7	793	2	US-09-539-879A-4	Sequence 4, Appli
151	594	5.7	793	2	US-08-895-590-4	Sequence 4, Appli
152	594	5.7	793	2	US-08-895-590-4	Sequence 4, Appli
153	451.5	4.3	305	2	US-10-162-012-23	Sequence 17, Appl
154	396.5	3.8	319	1	US-07-745-206A-17	Sequence 6309, Ap
155	396.5	3.8	319	1	US-08-311-363-17	Sequence 4, Appli
156	315.5	3.0	816	2	US-10-104-047-3657	Sequence 46, Appl
157	310.5	3.0	91	2	US-09-621-976-6309	Sequence 48, Appl
158	304.5	2.9	196	2	US-07-998-289B-4	Sequence 50, Appl
159	286	2.7	53	1	US-08-401-512-46	Sequence 51, Appl
160	266	2.5	53	1	US-08-401-512-48	Sequence 13, Appl
161	266	2.5	53	1	US-08-401-512-50	Sequence 52, Appl
162	263	2.5	53	1	US-08-401-512-51	Sequence 49, Appl
163	263	2.5	138	2	US-09-024-020B-13	Sequence 20223, A
164	263	2.5	138	2	US-09-425-043-13	Sequence 11, Appl
165	261	2.5	53	1	US-08-401-512-52	Sequence 10, Appl
166	258	2.5	53	1	US-08-401-512-47	Sequence 10, Appl
167	254	2.4	53	1	US-08-401-512-49	Sequence 10, Appl
168	248	2.4	386	2	US-09-248-796A-20223	Sequence 11, Appl
169	248	2.4	140	2	US-09-024-020B-11	Sequence 11, Appl
170	246.5	2.4	140	2	US-09-425-043-11	Sequence 10, Appl
171	237.5	2.3	150	2	US-09-024-020B-10	Sequence 10, Appl
172	237.5	2.3	150	2	US-09-425-043-10	Sequence 10, Appl

ALIGNMENTS

RESULT 1  
US-09-634-920-4  
; Sequence 4, Application US/09634920  
; Patent No. 6342357  
; GENERAL INFORMATION:  
; APPLICANT: Splawski, Igor  
; APPLICANT: Keating, Mark T.  
; TITLE OF INVENTION: SCNA AND METHODS FOR DETECTING SAME  
; FILE REFERENCE: 2323-155  
; CURRENT FILING DATE: 2000-08-09  
; PRIOR FILING DATE: 2000-03-17  
; PRIOR FILING DATE: 2000-03-17  
; PRIOR FILING DATE: 1999-08-09  
; NUMBER OF SEQ ID NOS: 4  
; SOFTWARE: PatentIn Ver. 2.0  
; SEQ ID NO 4  
; LENGTH: 2016  
; TYPE: PRT  
; ORGANISM: Homo sapiens  
US-09-634-920-4

173	230.5	2.2	398	2	US-10-162-012-21	Sequence 21, Appli
174	228.5	2.2	363	2	US-08-651-999A-4	Sequence 4, Appli
175	228.5	2.1	363	2	US-09-385-752-4	Sequence 4, Appli
176	225.5	2.1	439	2	US-09-248-796A-20222	Sequence 20222, A
177	225.5	1.8	138	2	US-09-024-020B-12	Sequence 12, Appl
178	187.5	1.8	138	2	US-09-425-043-12	Sequence 12, Appl
179	183.5	1.7	54	1	US-08-401-512-55	Sequence 56, Appl
180	183	1.7	968	2	US-08-651-999A-7	Sequence 7, Appli
181	183	1.7	968	2	US-09-385-752-7	Sequence 7, Appli
182	183	1.7	987	2	US-09-949-016-5914	Sequence 5914, Ap
183	183	1.7	987	2	US-09-949-016-10368	Sequence 10368, A
184	174	1.7	33	3	US-09-367-794-1	Sequence 1, Appli
185	173	1.6	696	2	US-08-906-865-4	Sequence 4, Appli
186	173	1.6	696	2	US-09-129-668-4	Sequence 945, App
187	172	1.6	705	2	US-09-538-092-945	Sequence 9700, Ap
188	172	1.6	713	2	US-09-949-016-9700	Sequence 13, Appl
189	171.5	1.6	532	2	US-10-162-012-13	Sequence 12, Appl
190	167	1.6	757	2	US-09-949-016-7121	Sequence 6, Appli
191	166.5	1.6	854	2	US-09-833-466-12	Sequence 1600, Ap
192	166.5	1.6	858	2	US-09-275-252A-6	Sequence 1600, Ap
193	166	1.6	35	2	US-09-657-276-1600	Sequence 9, Appli
194	166	1.6	35	2	US-10-162-012-9	Sequence 10, Appl
195	164.5	1.6	223	1	US-08-288-405A-10	Sequence 13, Appl
196	164.5	1.6	532	1	US-09-833-466-13	Sequence 4, Appli
197	158	1.5	806	2	US-09-275-252A-4	Sequence 53, Appl
198	155.5	1.5	616	2	US-08-401-512-53	Sequence 8, Appli
199	154.5	1.5	54	1	US-10-162-012-8	
200	153.5	1.5	446	2		

Query Match	99.5%	Score 10432.5;	DB 2;	Length 2016;
Best Local Similarity	99.5%;	Pred. No. 0;		
Matches 2006;	Conservative	2;	Mismatches	7;
			Indels	1;
			Gaps	1;
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DB	1	MANFLLPGTSSFRFTRESLAAIKRMAKQARGSTTLQESREGLPPEEAPRQLDQA	60	
QY	61	SKKLPDLYGNPPOELIGLEPLEDLPFYSTQKTFIVLNKGTIFRFSAATNALYVLSFPHI	120	
DB	61	SKKLPDLYGNPPOELIGLEPLEDLPFYSTQKTFIVLNKGTIFRFSAATNALYVLSFPHV	120	
QY	121	RAAAVKILVHSLFNMLIMCTILTNCFVMAHQDPPPMKTVYFTTAYTFESLVKLARG	180	
DB	121	RAAAVKILVHSLFNMLIMCTILTNCFVMAHQDPPPMKTVYFTTAYTFESLVKLARA	180	

See comments attached

181 FCLHPTFLRDPNNWLDPSVIMAYTTEFVGLNVSALRTFRVLRALKTISVIGLKTIV 240  
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 241 GALTQSVKVLADVNLVFCCLSVFALLGLQFMGNLPHKCVRNFTALNGTNGSVADGLV 300  
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 301 WESLDLYLSPENYLLKNGTSDVLLCGNSSDAGTCPEGYRCLKAGENPDHGYTSFDSFAW 360  
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 361 AFLALPRMTQDCWERYLQOTLSAGIKYIMFPMVLVIFLGSFYLVLNVLILAVVAMAYEON 420  
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 1021 PTKRTRFEGEGOGGTGDPVCPVPIAVASDTDDQEDENSIGTRESK-QBSQ 1079  
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 1140 TADMTNTABLLSQIPDLQGVKDPEDCFTGCVRRCPCCAVDTTQAPGVWRLRTCYH 1199  
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 1200 IVEHSWEPFTIIMLLSSGALAFEDIYLBERTIKVLEYADKMTYVYVLEMLKWA 1259  
 1260 YGFKKYFTNWCWLDPLIVDSVLSVANTLGAEMGPIKSLRTRLRALSRPEGM 1320

RESULT 2

US-09-840-125-4

; Sequence 4, Application US/09840125

; Patent No. 6787309

; GENERAL INFORMATION:

; APPLICANT: Splawski, Igor T.

; APPLICANT: Keating, Mark T.

; TITLE OF INVENTION: ALTERATIONS IN THE LONG QT SYNDROME GENES KVLQTL AND

; FILE REFERENCE: 2323-155

; CURRENT APPLICATION NUMBER: US/09/840,125

; CURRENT FILING DATE: 2001-04-24

; PRIOR APPLICATION NUMBER: 09/634,920

; PRIOR FILING DATE: 2000-08-09

; PRIOR APPLICATION NUMBER: 60/147,488

; PRIOR FILING DATE: 1999-08-09

; NUMBER OF SEQ ID NOS: 4

; SOFTWARE: PatentIn Ver. 2.0

; SEQ ID NO 4

; LENGTH: 2016

; TYPE: PR